## Welcome to Your DxTerity® Test Kit!

Instructions for Use

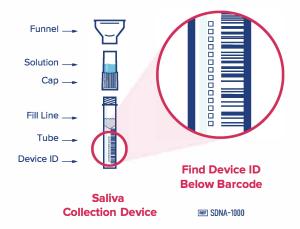


### **Step 1: Register Your Kit Now at DxTerity.com**

Register, Collect and Ship Same Day

To register your kit, create or log into your account, and type in the 14-digit Device ID located on your collection tube. The 14-digit Device ID must be entered correctly to process your test.

Open the kit and place all the contents on a clean, dry surface. **Ensure to register at time of collection.** Your 14-digit Device ID number will be assigned to you and registration date electronically stamped at the time.



# LABEL LEGEND Consult instructions for use ☐ Consult instructions for use ☐ Use by date (Collect saliva by) ☐ Catalog number A Caution, consult instructions for use # Temperature limit ☐ Manufacturer ☐ Batch code

#### **WARNING**

Individuals exhibiting severe COVID-19 warning symptoms are not allowed to proceed with kit registration and instead directed to seek emergency medical care. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by DxTerity Diagnostics, Inc. which is certified under CLIA and meets the requirements to perform high complexity tests. This product is authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. Saliva specimen will be collected at home or other collection sites outside of the healthcare setting from any individuals determined to be appropriate for COVID-19 testing by a HCP including from individuals without symptoms of COVID-19. Federal Law restricts this device to sale by or on the order of a licensed practitioner. Testing of saliva for individuals with or without symptoms of COVID-19 should be prescribed by healthcare provider. Children under the age of 18 may use this test, under adult supervision to assist, as needed, with the steps beyond spitting into the collection tube.

DxTerity Diagnostics Inc. 19500 South Rancho Way, Suite 116, Rancho Dominguez, CA 90220 | T. 310 537 7857 © DxTerity Inc. All Rights Reserved. Rx Only. For in vitro diagnostic use.

For use under Emergency Use Authorization (EUA) only. LAB-0309 03 / DXT-INST CARD-03